K103533 1/1

AOS

ADVANCED ORTHOPAEDIC SOLUTIONS

JAN 19 2011

8. SPECIAL 510(K) SUMMARY

SUMMARY PREPARED ON: November 30, 2010

SUBMITTED BY:
Advanced Orthopaedic Solutions, Inc.
386 Beech Avenue, Unit B6
Torrance, CA 90501
Phone: (310) 533-9966

CONTACT PERSON:
Julie Glendrange
Advanced Orthopaedic Solutions, Inc.
386 Beech Avenue, Unit B6
Torrance, CA 90501
Phone: (310) 533-9966

DEVICE NAME: AOS Extended Short (ES™) Trochanteric Nail
COMMON NAME: Intramedullary Fixation Rod
CLASSIFICATION: Class II, 21 CFR 888.3020 Intramedullary Fixation Rod

DEVICE CODE: HSB

SUBSTANTIALLY EQUIVALENT DEVICE: AOS Trochanteric Nail (K021008, Cleared June 20, 2002)

DEVICE DESCRIPTION: The AOS ES™ Trochanteric Nail is a Titanium intramedullary nail that is designed to enter the femur through the greater trochanter. It consists of an intramedullary nail, sliding lag screw, anti-rotation screw, locking screws and end cap.

INDICATIONS FOR USE: The AOS ES™ Trochanteric Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures.

SUBSTANTIAL EQUIVALENCE: Information presented supports substantial equivalence of the AOS ES™ Trochanteric Nail to the predicate device. The proposed nail has the same indications for use, is similar in geometry and design, has the same fundamental technology and is made of the same material (ASTM F136) as the predicate device. The ES Trochanteric Nail was tested against the predicate device through a bench bending analysis as well as a dimensional comparison. The testing resulted in substantial euqivent strength and geometry between the ES trochanteric nail and the short trochanteric nail.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Advanced Orthopaedic Solutions, Inc.
% Ms. Julie Glendrange
386 Beech Avenue, Unit B6
Torrance, CA 90501

JAN 19 2011

Re: K103533
Trade/Device Name: AOS ES Trochanteric Nail
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: II
Product Code: HSB
Dated: December 21, 2010
Received: December 22, 2010

Dear Ms. Glendrange:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K103533

Device Name: AOS Extended Short (ES™) Trochanteric Nail

Indications for Use:

The AOS ES™ Trochanteric Nail is intended to treat stable and unstable proximal fractures of the femur including pertrochanteric, intertrochanteric and high subtrochanteric fractures and combinations of these fractures.

Prescription Use: X AND/OR Over-The-Counter Use: ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103533